UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE: DAVOL, INC./C.R. BARD, INC., POLYPROPYLENE HERNIA MESH PRODUCTS LIABILITY LITIGATION

Case No. 2:18-md-2846

JUDGE EDMUND A. SARGUS, JR.
Magistrate Judge Kimberly A. Jolson

This document relates to:
Johns v. CR Bard et al.,
Case No. 2:18-cv-1509

MOTIONS IN LIMINE OPINION AND ORDER NO. 10

Plaintiff Steven Johns and Defendants C.R. Bard, Inc. and Davol, Inc. filed various motions in limine to exclude evidence in this case. Now before the Court are Defendants' Motion in Limine No. 3 to Exclude Reference to Irrelevant Bard Devices (ECF No. 176), Defendants' Motion in Limine No. 1 to Preclude any Evidence or Argument Concerning the Composix Kugel Ring Breaks and Recall (ECF No. 174), and Defendants' Motion to Seal Exhibits D, E, F, and G to Plaintiff's Supplemental Brief in Opposition to Defendants' Motion in Limine No. 1. (ECF No. 342.)

I. Background[1]

This case is the first bellwether trial, selected from thousands of cases in this multidistrict litigation ("MDL"), alleging "that defects in defendants' polypropylene hernia mesh products can lead to complications when implanted in patients, including adhesions, damage to organs, inflammatory and allergic responses, foreign body rejection, migration of the mesh, and infections." (No. 2:18-md-02846, ECF No. 1 at PageID #1–2.)[2] This includes the Ventralight ST,

[1] The Court assumes that the parties and other interested readers are familiar with the history of this case. For a more complete factual background, the reader is directed to the Court's summary judgment opinion and order. (ECF No. 309.)

[2] Unless otherwise noted, record citations are to the docket for this case, No. 18-cv-01509.

the device implanted in Plaintiff. The Ventralight ST is a prescription medical device used for hernia repairs. (ECF No. 309 at PageID #16717.) The Food and Drug Administration ("FDA") cleared it for use through the premarket notification § 510(k) process in 2010 and later cleared it for use with the Echo Positioning System in 2011. It is a multicomponent device made of a mesh, which consists of polypropylene, polyglycolic acid ("PGA") fibers, and a bioresorbable coating called "Sepra Technology" ("ST"). The ST-coated side of the mesh is placed against organs, such as the bowels, while the uncoated polypropylene side is placed against the fascia because the uncoated side maximizes tissue attachment and thus supports the hernia repair. (*Id.*)

Plaintiff brings this action to recover for injuries sustained as a result of the implantation of Defendants' allegedly defective Ventralight ST device. Plaintiff claims that Defendants knew that polypropylene is unsuitable for permanent implantation in the human body and that the PGA fibers created an increased inflammatory response. (*Id.*) The crux of Plaintiff's claims is that the ST coating on Ventralight ST devices resorbs too quickly. This leads to the exposure of bare polypropylene to internal organs and tissues, increasing the risk of potential complications. Plaintiff alleges that this occurrence led to omental adhesions after his laparoscopic hernia repair surgery in 2015. The adhesions were diagnosed during a subsequent laparoscopic surgery in October 2016 by Plaintiff's implanting surgeon. (*Id.* at PageID #16740, 16746.)[3] After summary judgment, the following claims remain for trial: design defect, under negligence and strict liability theories; failure to warn, under negligence and strict liability theories; breach of express warranty; breach of implied warranty; breach of implied warranty of merchantability; negligent misrepresentation; and punitive damages. (*Id.* at PageID #16727–65.) The Court bifurcated the

[3] The Court granted Defendants' motion for summary judgment on Plaintiff's other alleged injuries because Plaintiff failed to demonstrate a material fact dispute regarding causation. (ECF No. 309 at PageID #16740.)

trial into two separate phases, one for liability and one for punitive damages if Defendants are found liable. (ECF No. 330 at PageID #17883.) Now various motions in limine and other evidentiary motions are ripe for adjudication.

This opinion addresses four motions in limine that, broadly speaking, challenge the admissibility of evidence related to other devices (ECF Nos. 174, 176), as well as a related motion to seal (ECF No. 342). At the hearings on September 3 and September 10, 2020, the Court reserved judgment on part or all of each motion. (ECF No. 331 at PageID #17884; ECF No. 332 at PageID #17888.)

II. Legal Standards

"Neither the Federal Rules of Evidence nor the Federal Rules of Civil Procedure explicitly authorize a court to rule on an evidentiary motion *in limine*." *In re E.I. du Pont de Nemours & Co. C-8 Pers. Injury Litig.*, 348 F. Supp. 3d 698, 721 (S.D. Ohio 2016). The practice of ruling on such motions "has developed pursuant to the district court's inherent authority to manage the course of trials." *Luce v. United States*, 469 U.S. 38, 41 n.4 (1984). "The purpose of a motion *in limine* is to allow a court to rule on issues pertaining to evidence prior to trial to avoid delay and ensure an evenhanded and expedient trial." *In re E.I. du Pont*, 348 F. Supp. 3d at 721 (citing *Ind. Ins. Co. v. Gen. Elec. Co.*, 326 F. Supp. 2d 844, 846 (N.D. Ohio 2004)). However, courts are generally reluctant to grant broad exclusions of evidence before trial because "a court is almost always better situated during the actual trial to assess the value and utility of evidence." *Koch v. Koch Indus., Inc.*, 2 F. Supp. 2d 1385, 1388 (D. Kan. 1998); *accord Sperberg v. Goodyear Tire & Rubber Co.*, 519 F.2d 708, 712 (6th Cir. 1975). Unless a party proves that the evidence is clearly inadmissible on all potential grounds—a demanding requirement—"evidentiary rulings should be deferred until trial so that questions of foundation, relevancy and potential prejudice may be resolved in proper

context." *Ind. Ins. Co.*, 326 F. Supp. 2d at 846; *see also Koch*, 2 F. Supp. 2d at 1388 ("[A] court is almost always better situated during the actual trial to assess the value and utility of evidence."). The denial, in whole or in part, of a motion in limine does not give a party license to admit all evidence contemplated by the motion; it simply means that the Court cannot adjudicate the motion outside of the trial context. *Ind. Ins Co.*, 326 F. Supp. 2d at 846.

Relevant evidence is "evidence having any tendency to make the existence of any fact that is of consequence to the determination of the action more probable or less probable than it would be without the evidence." Fed. R. Evid. 401. "Irrelevant evidence is" inadmissible. Fed. R. Evid. 402. A court may exclude relevant evidence under Federal Rule of Evidence 403 "if its probative value is substantially outweighed by a danger of . . . unfair prejudice, confusing the issues, misleading the jury, undue delay, wasting time, or needlessly presenting cumulative evidence." Fed. R. Evid. 403. Evidentiary rulings are made subject to the district court's sound discretion. *Frye v. CSX Trans., Inc.*, 933 F.3d 591, 598 (6th Cir. 2019); *see also Paschal v. Flagstar Bank*, 295 F.3d 565, 576 (6th Cir. 2002) ("In reviewing the trial court's decision for an abuse of discretion, the appellate court must view the evidence in the light most favorable to its proponent, giving the evidence its maximum reasonable probative force and its minimum reasonable prejudicial value.").

III. Analysis

A. Defendants' Motion in Limine No. 3

In their motion, Defendants urge this Court to exclude references to other Bard devices. (ECF No. 176.) The Court granted this motion in limine on the basis that such evidence was character evidence forbidden by Rule 404. (ECF No. 322 at PageID# 17273; ECF No. 331 at PageID #17885.) However, the parties were permitted to brief whether this evidence is admissible

as an exception to the rule against character evidence provided in Rule 404(b)(2). (ECF No. 322 at PageID# 17273; ECF No. 331 at PageID #17885.)

Rule 404(a) prohibits character or propensity evidence, "[e]vidence of a person's character or character trait" used "to prove that on a particular occasion the person acted in accordance with the character or trait." Fed. R. Evid. 404(a).[4] Rule 404(b) prohibits evidence of other acts "to show that on a particular occasion the person acted in accordance with the character." Fed. R. Evid. 404(b)(1). In other words, the Federal Rules of Evidence do not permit parties to introduce evidence that tempts a jury to conclude that because a party acted badly before, he must have acted badly this time as well. *Old Chief v. United States*, 519 U.S. 172, 180–82 (1997). Rule 404(b)(2) provides exceptions to this general rule. Parties may introduce evidence of other crimes, wrongs or acts "for another purpose such as proving motive, opportunity, intent, preparation, plan, knowledge, identity, absence of mistake, or lack of accident." Fed. R. Evid. 404(b)(2).

The Sixth Circuit applies Rule 404(b) through a three-step process. This test requires that "(1) the 'other act' actually occurred, (2) the evidence is offered for a permissible purpose, and (3) its probative value is not substantially outweighed by unfair prejudice." *United States v. Carter*, 779 F.3d 623, 625 (6th Cir. 2015) (quoting *United States v. De Oleo*, 697 F.3d 338, 434 (6th Cir. 2012)). A second tripartite inquiry defines the second prong. Evidence is offered for a permissible purpose when (1) the purpose is one delineated by Rule 404(b)(2), "(2) that purpose is in issue, and (3)" the evidence is probative of that purpose. *United States v. Hardy*, 643 F.3d 143, 150–51 (6th Cir. 2011) (quoting *United States v. Jenkins*, 345 F.3d 928, 937 (6th Cir. 2003)); *United States v. Hazelwood*, 979 F.3d 398, 411 (6th Cir. 2020) (quoting *United States v. LaVictor*, 848 F.3d 428,

[4] Plaintiff argues that evidence of other devices made by Defendants is also admissible under the Utah Rules of Evidence (ECF No. 326 at PageID #17558), but federal courts sitting in diversity apply the Federal Rules of Evidence. *Gass v. Marriott Hotel Servs., Inc.*, 558 F.3d 419, 426 (6th Cir. 2009).

445–46 (6th Cir. 2017)). The gist of this approach is that the evidence of other acts must be consistent with Federal Rules of Evidence 104(b) (stating that when evidence depends on a fact, sufficient proof must be submitted to show the fact exists,), 401, 403, and 404(b)(2) to be admissible.

In his supplemental briefing, Plaintiff clarified that he seeks to introduce this evidence to demonstrate Defendants' knowledge that polypropylene should not be used in permanently implantable device based on previous evaluations, Defendants withholding of Material Safety Data Sheets ("MSDS") sheets from the FDA during the § 510(k) application process for various devices, and Defendants withholding of information from about polypropylene from their China team. (ECF No. 326 at PageID #17558–60.) He also argues that this evidence should be admissible for impeachment purposes. (*Id.* at PageID #17562–63.) The Court addresses notice, intent, and impeachment purposes in turn.

1. *Notice*

Plaintiff satisfies the three-part test in relation to Defendants' knowledge or notice of the risks posed by polypropylene. He meets the first prong because there is sufficient evidence that Defendants had various occasions to learn about the risks caused by polypropylene. Though Defendants dispute the meaning of these occasions, they do not truly dispute the underlying events, such as that the Kugel Hernia Mesh Patch has specifications referring to medical-grade polypropylene, a fact which both parties acknowledge. (ECF No. 326 at PageID #17559; ECF No. 339 at PageID #18507–08.)

As to the second prong, Plaintiff identifies a permissible use, knowledge, and Defendants' knowledge is material, or at issue, and the other-device litigation is probative of Defendants' knowledge of the risks presented by polypropylene mesh. Plaintiff's negligence claim turns in part

upon what Defendants knew or should have known in terms of the danger of adhesions from the polypropylene in the Ventralight ST, which tends to suggest that Defendants' decisions to push ahead with the ST coating was unreasonable in light of this knowledge.

Several examples offered by Plaintiff are worth exploring here. Most straightforwardly, Plaintiff refers to Defendants' "design failure modes and effect analysis" that it conducted on other devices using polypropylene. (ECF No. 326 at PageID #17561.) If Defendants performed internal analyses on other devices that would have put them on notice that polypropylene presents the risk of adhesions, then this evidence is admissible as non-character evidence.

Plaintiff also asserts that Defendants "circumvented the resin buying process to obtain food/commercial grade resin from third-party suppliers" and that the Defendants withheld multiple MSDSs from the FDA during the § 510(k) process. (ECF No. 326 at PageID #7561.) In an earlier motion in limine, Plaintiff explained the circumstances of the Marlex procurement more clearly, arguing that because of the Medical Application Causation statement in the Marlex MSDS about permanent implantation, Defendants sought to buy non-medical polypropylene. (ECF No. 234 at PageID #12860.) Defendants' prior purchasing conduct for other devices is admissible to the extent that it tends to prove that the Defendants knew polypropylene was dangerous and/or unsuitable for human implantation, which could include their understanding of what the Medical Application Caution in the Marlex MSDS meant, *i.e.* whether it spoke to safety or to prevent litigation. (*See* ECF No. 355 at PageID #18763–65 (holding that this type of evidence would be relevant, but that Roger Darois's testimony on this fact was inadmissible because he lacked personal knowledge).)

The same is true of evidence that in relation to prior devices, Defendants withheld the MSDSs from the FDA and other parts of their team in China. Such evidence speaks to Defendants'

understanding of the risks presented by polypropylene and is thus admissible under Rule 404(b)'s knowledge exception.

As to the third prong of this test, a limiting instruction explaining that evidence of other-device litigation may only be considered for Defendants' knowledge or notice cures any potential for prejudice or confusion. *United States v. Asher*, 910 F.3d 854, 862 (6th Cir. 2018). Thus, the third prong is satisfied as well.

Defendants raise several counterarguments, none of which is sufficient to demonstrate that evidence related to other-device litigation is irrelevant or unduly prejudicial. First, Defendants argue that many of the other devices made by Defendants do not use the same polypropylene resin, Marlex, and that Plaintiff's reference to non-medical grade polypropylene is not sufficient to tie the other polypropylene resins to the Marlex polypropylene used in the Ventralight ST. (ECF No. 339 at PageID #18506.) But Defendants themselves provide that connection, asserting that "*any* polypropylene mesh . . . presents the risk of adhesions when in contact with visceral structures." (*Id.*) Thus, it would seem that there need not be a more specific connection between the polypropylene used in the other devices and the Marlex polypropylene here. If all polypropylene is the same, then Defendants' knowledge of the risk of adhesions with other types of polypropylene tends to make it more likely that they knew or should have known that the Marlex polypropylene would present similar risks.

Relatedly, Defendants contend that there is no evidence that adhesions are caused specifically by Marlex polypropylene (*id.*at PageID #18505), that none of the other devices had an ST coating, which is pertinent because Plaintiff's claim is that the absorption rate of the ST coating caused his injury (ECF No. 176 at PageID #10197), that the other devices have significant design differences from the Ventralight ST device, and that the other devices are not predicate devices to

the Ventralight ST (*id.* at PageID #10196–97). But as this Court has explained before, Defendants cannot ignore the links in Plaintiff's chain of causation. (ECF No. 355 at PageID #18759.) Plaintiff claims that because the ST coating resorbed too quickly, the bare polypropylene mesh was exposed to Plaintiff's organs, causing adhesions. (*Id.*) Moreover, the fact that other devices were not made of Marlex polypropylene is not dispositive here because, as Defendants contend, adhesions can be caused by all polypropylene. Additionally, that some devices lacked an ST coating does nothing to diminish any of Defendants' knowledge that nonmedical grade polypropylene generally caused adhesions. And as with transvaginal and pelvic mesh devices, the differences between the Ventralight ST and other devices do not negate the probative value of the other-device evidence suggesting that Defendants knew or should have known that the exposure of bare polypropylene mesh causes adhesions.

Defendants finally argue that the presentation of other-device evidence would produce a mini-trial concern. (ECF No. 339 at PageID #18507.) But as with the transvaginal and pelvic mesh devices, any mini-trial concern is negated because knowledge is a discrete issue that does not require re-litigation and any risk of unfair prejudice or jury confusion is resolved with a limiting instruction. The Court is also confident that Defendants will point to the most persuasive differences between the devices and their methods of implantation, reducing any risk of unfair prejudice. *See id.* Much of Defendants' argument on this point also hinges on their assertion that there is no such thing as medical-grade polypropylene, meaning that they could not have known Marlex and other types of polypropylene not designed for medical usage were categorically dangerous. (*Id.*) The Court denied Defendants' motion in limine to exclude evidence of medical-grade polypropylene, concluding it was a jury question. (ECF No. 322 at PageID #17268.) Therefore, Defendants find no traction here.

This part of Defendants' motion is denied, but one caveat is warranted. Any evidence of other devices made by Defendants offered to prove Defendants' knowledge must be connected to Plaintiff's only injury that survived summary judgment—adhesions. Plaintiff's briefing was too general to determine whether evidence related to the polypropylene in other Bard devices had any connection to adhesions. As always, the burden of showing admissibility of evidence is on its proponent. *United States v. Brika*, 416 F.3d 514, 529 (6th Cir. 2005). Plaintiff must be able to connect other-device evidence demonstrating Defendants' knowledge of the risk of adhesions.

For these reasons, this part of Defendants' motion is denied.

2. *Impeachment or rebuttal*

Plaintiff argues that he should be permitted to introduce evidence of other devices made by Defendants to rebut or impeach testimony. (ECF No. 326 at PageID #17562.) However, Defendants contend that their motion in limine does not pertain to impeachment or rebuttal evidence. (ECF No. 339 at PageID #18508.) Thus, the Court declines to construe Defendants' motion in limine as reaching this issue. It is also inappropriate to consider Plaintiff's arguments outside of the trial context because he only speculates as to the possible venues of impeachment and rebuttal he may be required to pursue at trial.

It is unclear why Plaintiff raises this issue here. It appears that Plaintiff is not arguing that he should be permitted to introduce evidence of Defendants' character for untruthfulness pursuant to Federal Rule of Evidence 608, which is related to the rule against character evidence. But Plaintiff is clear that he hopes to refer to specific instances of conduct, which is not permitted under Rule 608. Instead, it appears that Plaintiff is referring to impeachment by contradiction via extrinsic evidence. The Court directed the parties to address whether what would otherwise be classified as character evidence under Rule 404 could be admitted under Rule 404(b)(2) for a non-

character purpose. Impeachment by specific contradiction is a wholly different matter. *See generally United States v. Craig*, 953 F.3d 898, 904–06 (6th Cir. 2020).

Plaintiff may have raised this issue to combat any good or positive character evidence that Defendants have always manufactured their devices in accordance with FDA guidelines and done so safely. (ECF No. 326 at PageID #17562.) But character or propensity evidence may be of bad *or* good character; Rule 404 makes no distinction. Fed. R. Evid. 404(a)(1), (b)(1). Therefore, Plaintiff would have no occasion to rebut evidence of Defendants' general good character because it would also be inadmissible propensity evidence. As a note of caution, the Court observes that, while bad character or propensity evidence is inadmissible, contradiction evidence to rebut testimony of Defendants' good character, which could conceivably creep into the trial, might change this conclusion.

In short, nothing in Plaintiff's briefing justifies addressing this issue at this moment.

B. Defendants' Motion in Limine No. 1

In Defendants' first motion in limine, they argue that evidence or argument regarding the Composix Kugel ring breaks and subsequent recall should be excluded. (ECF No. 174 at PageID #9979.) The Court granted this motion in part, concluding that this evidence constituted character evidence but again permitted the parties to brief whether the evidence could come in under an exception to the rule against character evidence, Rule 404(b)(2). (ECF No. 331 at PageID #17885.) On this issue, supplemental briefing was ordered. (*Id.*) The Court also permitted briefing regarding a *New York Times* article to address hearsay concerns. (ECF No. 322 at PageID #17273.)

1. Evidence of Composix Kugel ring breaks and Rule 404(b)(2)

In his briefing, Plaintiff purportedly identifies several non-character uses of evidence related to the Composix Kugel ring breaks and recall, including Defendants' knowledge,

Defendant's motive, and the lack of mistake and accident. (ECF No. 325 at PageID #17312.) Plaintiff describes evidence of events leading to issues with Defendants' quality management system, as well as the events underlying Defendants' efforts to bring ST products to market (ECF No. at PageID #17312–19.)

As to Defendants' knowledge of deficiencies in their quality management system discovered in relation to the Composix Kugel device (*id.* at PageID #17317–19), this evidence is admissible. In the Court's decision regarding Defendants' Motion in Limine No. 5, the Court concluded that evidence from third-party audits was permissible under Rule 404(b)(2) because FDA regulations help define the standard of care under Utah law and the same quality management system was in place for the Composix Kugel as for the Ventralight ST. (ECF No. 359 at PageID #18792.) There is no reason why evidence showing the same knowledge from different sources should be treated differently here. Plaintiff may introduce evidence related to the Composix Kugel Ring breaks and recall to show that Defendants knew or should have known that their quality management systems used for the Ventralight ST were not up to par.

Plaintiff also describes evidence regarding "the Zebra deal," which was to acquire ST technology. (ECF No. 325 at PageID #17313.) As a part of this deal, Defendants created a three-year plan, including an effort to rebrand the Composix Kugel, and Defendants focused on a speedy effort to bring ST technology to market to combat the financial losses from the Composix Kugel recall. (*Id.* at PageID #17314–15.) Although this evidence actually refers to another device, the Composix Kugel, and the events related to this device, the recall, this is not evidence of other acts that would fall within Rule 404(b). Instead, this is evidence about the how the Ventralight ST came to market and is relevant to the reasonableness of Defendants' conduct. This is not character evidence otherwise prohibited by Rule 404(a).

Defendants fail to raise any countervailing arguments. Defendants assert that Plaintiff did not address rule 404(b) issues or tie the evidence to the Ventralight ST. Further, Defendants assert that this evidence will prejudice them and prolong trial. (ECF No. 340 at PageID #18513–14.) The Court disagrees. Plaintiff showed in relation to Defendants' Motion in Limine No. 5 that Defendants used the same quality management system in the Composix Kugel and Ventralight ST devices. And as stated above, evidence of the Composix Kugel recall and how it influenced the decision-making process behind the Ventralight ST is not Rule 404(b) evidence at all. As to any Rule 403 arguments, a limiting instruction to the jury that they are to consider Composix Kugel only as evidence of Defendants' knowledge and how the recall influenced Defendants' conduct related to the Ventralight ST device will be sufficient.

Accordingly, this part of Defendants' motion is denied.

2. The New York Times *article and hearsay*

Finally, Defendants argue that a *New York Times* article criticizing Defendants for the Composix Kugel recall is inadmissible because it is irrelevant, unfairly prejudicial, and inadmissible hearsay. (ECF No. 174 at PageID #9987; ECF No. 340 at PageID #18519–52.) The admissibility of the article is resolvable solely on the hearsay issue.

Hearsay is an out-of-court statement offered for the truth of the matter asserted. Fed. R. Evid. 801(a), (c). Unless a statement falls within an exception or exclusion set forth by the Federal Rules of Evidence, federal statute, or Supreme Court precedent, hearsay is inadmissible. Fed. R. Evid. 802. If a statement offered for the truth of the matter asserted contains another statement offered for the truth of the matter asserted, this presents a double-hearsay, multiple-hearsay, or hearsay-within-hearsay issue. *Back v. Nestle USA, Inc.*, 694 F.3d 571, 577–78 (6th Cir. 2012). "Hearsay within hearsay is not excluded by the rule against hearsay if each part of the combined

statement conforms with an exception to the rule," Fed. R. Evid. 805, or an exclusion from the rule against hearsay, *see Back*, 694 F.3d at 577–78 (applying this rule to statements falling under Rule 801(d)(2)(D), an exclusion from, rather than exception to, hearsay).

In *Parker v. Winwood*, an excerpt from an interview taken from a book was deemed to be inadmissible. 938 F.3d 833, 836–37 (6th Cir. 2019). Although the book passage recounting the interviewee's statements fell within the ancient document exception to hearsay, Federal Rule of Evidence 803(16), the declarant's statements did not fall within an exception to the rule against hearsay. *Id.* In the same case, a webpage printout of an article containing an interview was inadmissible because of the three layers of hearsay present—the webpage printout, the article, and the underlying declarant's statements—two layers did not fall within an exclusion or exception to hearsay. *Id.* at 837. Although the webpage was a party admission under Federal Rule of Evidence 801(d)(2)(A) or (B), neither the 1988 article from Billboard Magazine nor the quoted statements from a musician fell within a hearsay exception or exclusion. *Id.* at 837–38.

Plaintiff seeks to admit a *New York Times* article that contains statements from Bard and from Harold Pellerite of Quintiles Consulting Co., the company Defendants hired to perform an audit in relation to the Composix Kugel ring breaks and recall. Plaintiff offers them for the truth of the matters asserted, including information about device complaints, deficiencies, etc. (ECF No. 325 at PageID #17308.) Any statements made by Bard clearly fall under Rule 801(d)(2) as an opposing party statement. Fed. R. Evid. 801(d)(2). And the Court assumes for the sake of argument that Plaintiff is correct that Pellerite's statements to the Times should be attributed to Bard as its agent and that his statements are thus non-hearsay under Rule 801(d)(2)(D). (*Id.* at 17308–12.)

But Rule 801 only covers one layer of hearsay—the statements made to the Times. Plaintiff does not identify an exception to or exclusion from the rule against hearsay that would cover the

New York Times's assertion of these statements, which it made by publishing the article. The existence of this second level and the resultant inadmissibility is eminently clear from *Parker*—articles containing interviews are double hearsay and articles that do not fall within the ancient documents exception to hearsay are generally inadmissible. No other exclusion or exception appears to apply to the article, and so it is inadmissible hearsay.

Accordingly, this portion of Defendants' motion in limine is granted.

C. Motion to Seal

In response to Plaintiff's Supplemental Brief in Opposition to Defendants' Motion in Limine No. 1 (ECF No. 325), Defendants filed a motion to seal Plaintiff's Exhibits D, E, F, and G attached to his supplemental brief. (ECF No. 342.) Plaintiff cites these exhibits in support of his argument that the *New York Times* article is not hearsay because Pellerite was Defendants' agent. (ECF No. 325 at PageID #17308–12.) Defendants argue that these exhibits should be permanently sealed because they violate Local Rule 7.2(e) and that they contain Defendants' confidential and proprietary documents. (ECF No. 342 at PageID #18530.)

A district court may enter a protective order during discovery on a mere showing of "good cause," Fed. R. Civ. P. 26(c)(1), but "'very different considerations apply' . . . 'when the parties place material in the court record.'" *Shane Grp., Inc. v. Blue Cross Blue Shield of Mich.*, 825 F.3d 299, 305 (6th Cir. 2016) (citations omitted). Whether to seal records is a decision left to the sound discretion of the district court. *See Kondash v. Kia Motors Am., Inc.*, 767 F. App'x 635, 637 (6th Cir. 2019) (citing *Meyer v. Goldberg, Inc. v. Fisher Foods, Inc.*, 823 F.2d 159, 161 (6th Cir. 1983)). However, a district "court's discretion to seal its record is bounded by a 'long-established legal tradition' of the 'presumptive right of the public to inspect and copy judicial documents and files.'" *Rudd Equip. Co., Inc. v. John Deere Constr. & Forestry Co.*, 834 F.3d 589, 593 (6th Cir. 2016)

(quoting *In re Knoxville News-Sentinel Co., Inc.*, 723 F.2d 470, 747 (6th Cir. 1983)). This results in a level of deference less than "the traditional scope of narrow review reserved for discretionary decisions based on first-hand observations." *Kondash*, 767 F. App'x at 637.

"'[T]he public has a strong interest in obtaining the information contained in the court record,'" thus the moving party has a "heavy" burden of overcoming a "'strong presumption in favor of openness' as to court records." *Id.* (citations omitted). Ultimately, the moving party must show that the public interest in accessing the records is outweighed by the moving party's interest in sealing the records. *Id.* at 635. To meet this burden, the moving party must "analyze in detail, document by document, the propriety of secrecy, providing reasons and legal citations." *Shane*, 825 F.3d at 305. "Ultimately, the movant must show that 'disclosure will work a clearly defined and serious injury . . . . And in delineating the injury to be prevented, specificity is essential.'" *Id.* at 307–08 (citations omitted).

Defendants meet their burden by a nose. Defendants identify their interest in sealing the records as a loss of a competitive advantage. (ECF No. 342 at PageID #18534.) Any risk of loss of competitive advantage is relatively small, meaning Defendants' interests in sealing the documents are weak. In the cases that Defendants cite, the courts heavily weighted the risk of a loss of a competitive advantage when the information the party sought to have sealed pertained to business strategies, sales statistics, financial information, and design plans. *London Comput. Sys. v. Zillow, Inc.*, No. 1:18-cv-696, 2019 WL 4110516, at *4 (S.D. Ohio Aug. 29, 2019); *Proctor & Gamble Co. v. Ranir, LLC*, No. 1:17-cv-185, 2017 WL 3537195, at *3 (S.D. Ohio Aug. 17, 2017). This makes sense because this information gives competitors a direct window into a party's product, its commercial success, and its financial health. The same is true of the comparative hernia recurrence data from the Americas Hernia Society Quality Collaborative Foundation, which was

permanently sealed in this case, because the data indicates how successful the Bard devices are in relation to competitor devices. (ECF No. 359 at PageID #18788.) But the sealed exhibits here are audits pertaining to the adequacy of Defendants' quality management systems in manufacturing and marketing the Composix Kugel device. The benefit to a competitor from knowing the specific inadequacies of Defendants' quality management system is not as indicative of the success of the product or the financial health of Defendants—at least, this is the case without further explanation or qualification from Defendants. Still, Defendants have shown at least some interest at stake in sealing these documents.

On the other hand, Defendants demonstrate with great specificity that the public has no interest in the content of these exhibits. "The public has an interest in ascertaining what evidence and records the District Court . . . ha[s] relied upon in reaching [its] decisions." *Brown & Williamson Tobacco Corp. v. F.T.C.*, 710 F.2d 1165, 1181 (6th Cir. 1983). Here, the Court assumed without deciding that Pellerite was Defendants' agent and concluded that the article was inadmissible because Plaintiff failed to address one layer of the double hearsay—the *New York Times*'s publication of the underlying statements. Therefore, there was no occasion to actually determine whether Pellerite was in fact Defendants' agent under Rule 801(d)(2)(D). Accordingly, the Court did not rely upon Exhibits D, E, F, and G to reach its decision regarding Defendants' Motion in Limine No. 1.

Even if it had been necessary to decide whether Pellerite was Defendants' agent, the exhibits in question do little to establish that Pellerite was Defendants' agent when he was speaking to the *New York Times*. Most of Plaintiff's supplemental brief is aimed at telling a story about Defendants' bad behavior in relation to the Composix Kugel device. Exhibit D summarizes a conference call that Pellerite was on during the audit, Exhibit E is part of the Quintiles Audit of

the Composix Kugel device, Exhibit F is a memorandum sent to Defendants' General Counsel about the regulatory assessment of the Composix Kugel device, and Exhibit G is a series of emails discussing the Composix Kugel audit. None of these documents describes the relationship between Pellerite and Defendants. At best, the exhibits show that Pellerite was an employee at Quintiles, the consulting agency hired to do the Composix Kugel audit. This does nothing to show that Pellerite was Defendants' agent in any sense, much less when he was speaking to the *New York Times*. In short, the Court could not have relied on the exhibits even if it had decided the agency question in reaching its holding that the *New York Times* article is inadmissible hearsay. Therefore, the public has no interest in the documents.

With this particular instance in mind, the Court notes that Plaintiff has more than once attached exhibits that contain Defendants' private and confidential records which have little to do with the issues presented. In September, the Court suggested as much, ordering that Plaintiff file a response explaining why certain exhibits were necessary to decide certain pending motions. (ECF No. 319.) Plaintiff admitted to attaching unnecessary exhibits by withdrawing several, explaining that some had even been "inadvertently included." (ECF No. 347 at PageID #18675–76.) One of the withdrawn exhibits included the Quintiles Audit, attached as Exhibit K to Plaintiff's Opposition to Defendants' Motion in Limine No. 5. (*Id.* at PageID #18675; ECF Nos. 190-10 to 190-15.) The Court is inclined to interpret Rule 7.2(e)'s requirement that submitted evidence "be limited to that necessary for decision" generously because "[o]ur adversary system is designed around the premise that the parties know what is best for them, and are responsible for advancing the facts and arguments entitling them to relief." *Greenlaw v. United States*, 554 U.S. 237, 244 (2008) (quoting *Castro v. United States*, 540 U.S. 375, 386 (2003) (Scalia, J., concurring in part and concurring in judgment)). But it is inefficient to adjudicate motions to seal documents

that do not assist the Court in resolving the legal questions before it and do not streamline evidentiary issues ahead trial. This is the last pending motion to seal in this case, but the parties should bear this in mind for future bellwether cases.

Accordingly, Defendants' motion to seal is granted.

IV. Conclusion

Accordingly, the remainder of Defendants' Motion in Limine No. 3 (ECF No. 176) is **DENIED IN PART**, the remainder of Defendants' Motion in Limine No. 1 (ECF No. 174) is **DENIED IN PART AND GRANTED IN PART**, and Defendants' Motion to Seal (ECF No. 342) is **GRANTED.**

IT IS SO ORDERED.

1/11/2021
DATE

s/Edmund A. Sargus, Jr.
EDMUND A. SARGUS, JR.
UNITED STATES DISTRICT JUDGE